SUNBURN RELIEF GEL- lidocaine hcl gel
Vi-Jon, LLC

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Mountain Falls 005.002/ 005AC-AD Sunburn Relief Gel
005

Active ingredient

Lidocaine HCl 0.5%

Purpose

External analgesic

Uses

for the temporary relief of pain and itching associated with

- minor burns
- sunburn
- minor cuts
- scrapes
- insect bites
- minor skin irritations

Warnings

For external use only

When using this product avoid contact with the eyes

When using this product

avoid contact with the eyes

Do not use

in large quantities, particularly over raw surfaces or blistered areas

Stop use and ask a doctor if

condition worsens, or if symptoms persist for more than 7 days or clean up and occur again within a few days

Keep out of reach of children

If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- adults and children 2 years of age and older: apply to affected area not more than 3 to 4 times daily
- children under 2 years of age: ask a doctor

Inactive ingredients

water, propylene glycol, glycerin, Aloe barbadensis leaf juice, triethanolamine, isopropyl alcohol, polysorbate 80, carbomer, benzyl alcohol, menthol, disodium EDTA, blue 1, yellow 5

*This product is not manufactured or distributed by Bayer, distributor of Solarcaine Cool Aloe Burn Relief

Formula

Manufactured by: Vi-Jon, Inc., St. Louis, MO 63114

Questions or comments? 1-888-593-0593

Made in the USA with US and foreign parts

principal display panel

Mountain falls

*Compare to Solarcaine

with aloe vera

helps returned moisture to sunburned skin

with lidocaine HCl

doctor tested

SUNBURN RELIEF GEL

PAIN RELIEVING GEL

NET WT 8 OZ (226 g)

SUNBURN RELIEF GEL

lidocaine hcl gel

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:0869-0005
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
LIDOCAINE HYDROCHLORIDE (UNII: V13007Z41A) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE HYDROCHLORIDE ANHYDROUS	5.05 g in 1 g

Inactive Ingredients	
Ingredient Name	**Strength**
WATER (UNII: 059QF0KO0R)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
GLYCERIN (UNII: PDC6A3C0OX)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
TROLAMINE (UNII: 9O3K93S3TK)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
CARBOXYPOLYMETHYLENE (UNII: 0A5MM307FC)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
MENTHOL (UNII: L7T10EIP3A)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0869-0005-34	226 g in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	01/10/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	01/10/2017	

Labeler - Vi-Jon, LLC (790752542)

Registrant - Vi-Jon, LLC (790752542)

Establishment

Name	Address	ID/FEI	Business Operations
Vi-Jon, LLC		790752542	manufacture(0869-0005)

Establishment

Name	Address	ID/FEI	Business Operations
Vi-Jon, LLC		088520668	manufacture(0869-0005)

Revised: 8/2021 Vi-Jon, LLC